K012193 p1/2

JUL 11 2002

510(k) Summary
of Safety and Effectiveness
OrthoGuard AB Antimicrobial Sleeve

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	9 July 2002
Contact Person:	Jeff F. Doerzbacher Manager, Clinical/Regulatory Affairs
Proprietary Name:	OrthoGuard AB Antimicrobial Sleeve
Common Name:	Antimicrobial Pin/Wire Sleeve
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Product Code and Panel Code:	JEC, NJA – Orthopedics/87

Predicate Device / Substantial Equivalence Information

The OrthoGuard AB Antimicrobial Sleeve is similar to the following devices:

Smith & Nephew External Fixation System (K994143)
EBI X Dyna Fix System SC Bone Screws (K961433)
Antimicrobial Multi-Lumen Central Venous Catheter (K900263)
Niagara Dialysis Catheter (K965178)
Bio-Guard AB Coated Catheter (K863354)
Antimicrobial Peritoneal Dialysis Coil Catheter (K961392)

All of the devices listed above are either used for orthopaedic use and/or contain antimicrobial agents, and are considered substantially equivalent to the OrthoGuard AB Antimicrobial Sleeve.

Device Description

The OrthoGuard AB Antimicrobial Sleeve consists of polyurethane tubing coated on the inner and outer surfaces with an antimicrobial coating of gentamicin complexed with lauryl sulfate in a matrix of nitrocellulose and polyurethane.

The OrthoGuard AB Antimicrobial Sleeve is provided at a maximum length for the longest pin/wire length and can be cut to desired lengths for smaller lengths of pins and wires selected for bone fixation. OrthoGuard AB Antimicrobial Sleeves are available in splined (longitudinal internal ridges for interference fit) or non-splined design in various diameters to match currently marketed orthopaedic pin/wire diameters.

Intended Use

The OrthoGuard AB Antimicrobial Sleeve is intended to be used as an accessory surrounding orthopaedic pins and wires during external fixation of bones. The OrthoGuard AB Antimicrobial Sleeve is indicated to inhibit bacterial colonization on the pin/wire.

Technological Characteristics

Although the OrthoGuard AB Antimicrobial Sleeve is not identical to the identified predicate devices, the intended use and material composition are substantially equivalent to the characteristics found in one or more of the legally marketed predicate devices. Any differences that exist do not significantly affect the safety and effectiveness of the OrthoGuard AB Antimicrobial Sleeve

Performance Characteristics

The OrthoGuard AB Antimicrobial Sleeve was subjected to the following testing and analyses: in-vitro elution tests, in-vivo elution tests, ETO sterilization validation study, packaging integrity test, ETO residual tests, product design configuration tests, coating adherence/consistency/conformity tests, microbial activity tests, antimicrobial release rate tests, fatigue (in-vitro) tests, product stability tests, biocompatibility tests, and quality control tests. The data from these tests support the safety and effectiveness of the device and substantial equivalence to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Mr. Jeff F. Doerzbacher
Manager, Clinical/Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K012193
Trade/Device Name: OrthoGuard AB Antimicrobial Sleeve
Regulation Number: 21 CFR §888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JEC, NJA
Dated: May 15, 2002
Received: May 16, 2002

Dear Mr. Doerzbacher;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

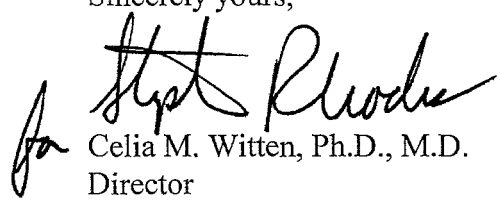
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Premarket Notification
Indications Enclosure

510(k) Number: K012193

Device Name: OrthoGuard AB Antimicrobial Sleeve

Indications for Use:

The OrthoGuard AB Antimicrobial Sleeve is intended to be used as an accessory surrounding orthopaedic pins and wires during external fixation of bones. The OrthoGuard AB Antimicrobial Sleeve is indicated to inhibit bacterial colonization on the pin/wire.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012193